

## Message Text

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PAGE 01 STATE 170722  
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E.O. 11652: N/A

TAGS: EEC, SENV, ETRD

SUBJECT: US/EC MEETING ON TOXIC SUBSTANCES

1. SUMMARY. THE EUROPEAN COMMUNITIES AND THE U.S. MET JUNE 29 AND 30 IN WASHINGTON TO DISCUSS QUESTIONS ARISING OUT OF THE IMPLEMENTATION OF TOXIC SUBSTANCES REGULATIONS IN THE AREAS OF PRE-MARKETING AND PRE-MANUFACTURING NOTIFICATION. THE COMMISSION -- BACKED UP BY REPRESENTATIVES OF SOME MEMBER GOVERNMENTS -- CAME PREPARED TO NEGOTIATE ON MODALITIES FOR APPLYING THE U.S. TOXIC SUBSTANCES CONTROL ACT (TSCA) AND SIMILAR EC LEGISLATION.

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PAGE 02 STATE 170722

EPA ASSISTANT ADMINISTRATOR JELLINEK EXPLAINED IN DETAIL WHY DOMESTIC REGULATORY PROCEDURES AND THE CURRENT STATUS OF TSCA IMPLEMENTATION WOULD MAKE NEGOTIATIONS AS SUCH IMPOSSIBLE. THE FIRST DAY WAS DEVOTED PRIMARILY TO EXPLANATIONS BY EPA OF HOW IT ENVISAGES ITS PROPOSED PRE-MANUFACTURING REGULATIONS FOR NEW CHEMICALS, WHICH IT HOPES TO PUBLISH IN SEPTEMBER. THE EC OBTAINED A MUCH

BETTER UNDERSTANDING OF THE DIRECTION IN WHICH THE EPA IS HEADING. PRE-MANUFACTURING REGULATIONS WILL BECOME FINAL 30 DAYS AFTER EPA PUBLISHES INVENTORY OF CURRENT CHEMICALS IN TRADE (DUE JANUARY 1979). COMMISSION HEAD OF

DELEGATION (CARPENTIER) WAS SOMEWHAT DISAPPOINTED THE FIRST DAY BY THE "TECHNICAL LEVEL" OF DISCUSSIONS, BUT AFTERWARDS BETTER UNDERSTOOD THAT SUCH SCIENTIFIC GROUNDWORK ESSENTIAL BEFORE POLICY ISSUES COULD EVEN BE ADDRESSED. SECOND DAY FOCUSED ON COMMUNITY'S LIST OF ELEVEN POSSIBLE TOPICS FOR AGREEMENT. TWO SIDES AGREED THAT SOME OF THESE APPEARED APPROPRIATE FOR BILATERAL DISCUSSIONS, THAT SOME COULD BE DEFERRED, AND THAT OTHERS CLEARLY APPROPRIATE FOR FOLLOW UP IN ONGOING OECD WORK. EPA MADE IT CLEAR THAT FURTHER INFORMATIONAL-TYPE MEETINGS WOULD HAVE TO TAKE PLACE IN A BROADER CONTEXT (POSSIBLY THE OECD), BUT THAT JELLINEK WOULD BE WILLING TO MEET BILATERALLY WITH THE COMMISSION (PREFERABLY IN BRUSSELS) IN THE FALL ON APPROPRIATE REGULATORY SUBJECTS. CARPENTIER OBVIOUSLY HOPED FOR MORE, BUT SEEMED RELATIVELY PLEASED THAT ANOTHER BILATERAL IS SCHEDULED. END SUMMARY.

2. CONTENTS OF THIS CABLE ARE FYI ONLY FOR INFO ADDRESSES AND SHOULD NOT BE DISCUSSED WITH HOST GOVERNMENTS.

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PAGE 03 STATE 170722

3. FIRST DAY EPA DISCUSSED IN DETAIL ITS THINKING ON PROPOSED REGULATIONS ON NEW CHEMICALS, AND PROCEDURES IT MUST FOLLOW. EC DELEGATION FILLED IN MANY INFORMATION GAPS, AND IT APPEARED THAT EPA ASSUAGED SOMEWHAT EC'S FEARS THAT MAJOR TRADE PROBLEMS COULD DEVELOP WHEN REGULATIONS BECOME FINAL IN FEBRUARY 1979. FACT THAT EXTENSIVE TESTING IS VOLUNTARY UNLESS EPA TAKES POSITIVE ACTION REGARDING IT ON A CASE-BY-CASE BASIS UNDER SECTION FOUR WAS APPARENTLY NEW TO MANY MEMBERS OF THE EC DELEGATION FOR EXAMPLE. CARPENTIER DID COMPLAIN THAT EPA'S PRESENT THINKING DIFFERS FROM EXPLANATIONS EC RECEIVED AT LAST MEETING IN JANUARY. JELLINEK REPLIED THAT NEW PERSONNEL HAD INDEED LED TO NEW APPROACH, BUT THAT HE ENVISAGED NO RADICAL CHANGES IN FUTURE.

4. DISCUSSION SECOND DAY FOCUSED ON EC'S 11 POINTS:  
-- A. THE HARMONIZATION OF CATEGORIES AND METHODS FOR THE NECESSARY TESTS FOR THE EVALUATION OF TOXICITY; ECOTOXICITY AND THE IMPACT ON THE ENVIRONMENT OF CHEMICAL SUBSTANCES. EPA SAID THAT OECD IS APPROPRIATE FORUM. CARPENTIER AGREED THAT OECD WORK SHOULD NOT BE

DUPLICATED, BUT WOULD STILL LIKE THIS AS SUBJECT FOR US/EC BILATERALS. EPA DID SAY IT MIGHT DISCUSS, BUT NOT NECESSARILY AGREE ON, KINDS OF TESTS TO INCLUDE IN THE BASE SET OF DATA.

-- B. THE MUTUAL RECOGNITION OF THE BASIC DATA REQUIRED TO PRODUCE THE DOCUMENTS OF NOTIFICATION. TWO SIDES AGREED THAT THIS WAS AN APPROPRIATE SUBJECT FOR BILATERAL DISCUSSIONS, ALTHOUGH AGREEMENT ON THE SAME TESTING REQUIREMENTS MAY NOT BE LIKELY IN THE NEAR FUTURE.

-- C. THE MUTUAL ACCREDITATION OF LABORATORIES RESPONSIBLE FOR CARRYING OUT THE TESTS AND THE VERIFICATION OF RESULTS. THIS IS ONE OF THE MOST CONTROVERSIAL TOPICS IN THE WHOLE AREA. GUIDELINES FOR LIMITED OFFICIAL USE

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PAGE 04 STATE 170722

GOOD LABORATORY PRACTICES IS A PRIME OECD TOPIC. EPA POINTED OUT THAT IT "AUDITS" INDUSTRY LABORATORIES, AND DOES NOT "ACCREDIT". EPA HAS HAD NO PROBLEMS DEALING DIRECTLY WITH FOREIGN MANUFACTURERS IN OTHER AREAS (PESTICIDES, AUTOMOBILES) WHO HOPE TO EXPORT TO THE U.S., AND ASSUMES THAT EC WILL NOT HAVE PROBLEMS DEALING DIRECTLY WITH AMERICAN COMPANIES WHO WISH TO EXPORT TO EUROPE. EC LIKELY TO CONTINUE TO PRESS ON SUBJECT OF MUTUAL ACCREDITATION, BUT THERE IS NO AREA IN WHICH TO AGREE, IN US VIEWPOINT, OTHER THAN THE DEVELOPMENT OF GUIDELINES.

-- D. THE ESTABLISHMENT OF PROCEDURES FOR THE EVALUATION OF RISKS TO HUMAN BEINGS AND THE ENVIRONMENT CAUSED BY CHEMICAL SUBSTANCES. BOTH SIDES AGREED THAT DISCUSSION OF THIS TOPIC COULD BE DEFERRED.

-- E. THE APPLICATION OF THE TSCA AND OF THE CORRESPONDING COMMUNITY LEGISLATION TO CHEMICAL SUBSTANCES CONTAINED IN MANUFACTURED PRODUCTS AND PREPARATIONS. IT WAS AGREED THAT THIS IS AN APPROPRIATE TOPIC FOR BILATERAL DISCUSSIONS.

-- F. THE PROCEDURES FOR ENSURING THE MUTUAL RESPECT OF THE CONFIDENTIAL NATURE OF CERTAIN DATA. US NOTED THAT TSCA PERMITS DISCLOSURES OF HEALTH AND SAFETY DATA BUT REQUIRES PROTECTION OF ALL OTHER PROPRIETARY INFORMATION, AND SAID THAT THE CURRENT OECD PROJECT IS APPROPRIATE FOR FOLLOW-UP.

-- G. THE LAWS OF THE INDIVIDUAL STATES OF THE UNITED STATES AS COMPARED WITH FEDERAL LAW REGARDING CONTROLS OF TOXIC CHEMICAL SUBSTANCES. EPA PROVIDED A COPY OF LIMITED OFFICIAL USE

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PAGE 05 STATE 170722

A LEGAL DISCUSSION DOCUMENT FROM EPA COUNSEL, NOTED THAT THE PROBLEM IS MORE THEORETICAL THAN REAL SINCE STATES WILL PROBABLY NOT WANT TO LEGISLATE IN THIS AREA, AND AGREED TO DISCUSS FURTHER WITH THE EC IF NECESSARY. (NOTE: DEPARTMENT LAWYERS ARE ALSO LOOKING INTO THIS QUESTION.)

-- H. METHODS OF DIVIDING THE COSTS ARISING FROM THE IMPLEMENTATION OF THE TOXIC SUBSTANCES CONTROL ACT AND OF THE CORRESPONDING COMMUNITY LEGISLATION. DISCUSSION WAS LIMITED TO DESCRIPTION OF EC AND U.S. SYSTEMS. U.S. INDICATED WILLINGNESS TO DISCUSS FURTHER.

-- I. THE ESTABLISHMENT OF PRIORITY LISTS OF EXISTING CHEMICAL SUBSTANCES WHICH COULD WELL BE THE SUBJECT OF SPECIAL SURVEILLANCE AND MONITORING MEASURES. BOTH SIDES AGREED THAT DISCUSSION COULD BE DEFERRED, THAT THE FOCUS SHOULD BE ON CRITERIA RATHER THAN LISTS, AND THAT THE WORLD HEALTH ORGANIZATION MIGHT HAVE A ROLE TO PLAY.

-- J. THE HARMONIZATION OF INVENTORIES OF CHEMICAL SUBSTANCES. EC SAID THAT IF IT DECIDES TO ESTABLISH AN INVENTORY IT COULD BENEFIT FROM U.S. EXPERIENCE. EPA AGREED TO SHARE INFORMATION.

-- K. THE STUDY OF THE POSSIBILITIES FOR COOPERATION IN THE FIELD OF RESEARCH. THIS TOPIC NEEDS FURTHER INVESTIGATION BY BOTH SIDES BEFORE BILATERAL DISCUSSIONS COULD BE USEFUL.

5. U.S. NOTED THAT EPA WILL SET 60-DAY DEADLINE IN WHICH TO RECEIVE WRITTEN COMMENTS AFTER IT PUBLISHES PROPOSED RESOLUTIONS FOR NEW CHEMICALS IN SEPTEMBER. U.S. INDUSTRY, FOREIGN BUSINESSES, FOREIGN GOVERNMENTS AND ENVIRONMENTAL INTEREST GROUPS MUST ALL BE HEARD FROM. FOR THE PURPOSE OF PROVIDING CLARIFICATION AND  
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PAGE 06 STATE 170722

ANSWERING QUESTIONS, THE U.S. WOULD LIKE TO HAVE ONE GENERAL MEETING FOR ALL INTERESTED COUNTRIES. EC SUGGESTED THAT U.S. CONVENE SUCH A MEETING UNDER OECD AUSPICES. EPA MADE NO COMMITMENT BUT DEPARTMENT AND EPA ARE CONSIDERING THIS IDEA. TO THE EXTENT THAT THE ISSUE IS HARMONIZATION OF THE IMPLEMENTATION OF LEGISLATION, THE U.S. IS WILLING TO DEAL DIRECTLY WITH EC

COMMISSION AND AGREED TO MEET BILATERALLY WITH  
COMMISSION IN THE FALL, PROBABLY IN BRUSSELS.

6. COMMENT: IT IS OBVIOUS THAT CARPENTIER WOULD HAVE  
LIKED MORE, BUT HE NOW UNDERSTANDS MUCH BETTER U.S.  
REGULATORY PROCESS, AND EPA PLAN OF ACTION. HE DID  
OBTAIN COMMITMENT TO A BILATERAL MEETING AFTER PROPOSED  
TSCA PRE-MANUFACTURING REGULATIONS ARE PUBLISHED. IT  
APPEARED THAT CARPENTIER WAS FAR OUT IN FRONT OF HIS  
COLLEAGUES IN PUSHING FOR "AGREEMENT", AND NOT AS  
UNDERSTANDING OF REASONS WHY EPA CANNOT REACH ACTUAL  
AGREEMENT ON FEDERAL REGULATIONS BEFORE THEY ARE EVEN  
COMMENTED UPON BY U.S. INDUSTRY AND OTHER FOREIGN  
GOVERNMENTS. EPA INDICATED WILLINGNESS TO GO AS FAR  
AS IT COULD IN EXCHANGING INFORMATION WITH COMMISSION  
AND AVOIDING POTENTIAL PROBLEMS IN CONFLICTING  
REGULATIONS. VANCE

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